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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,480	02/14/2006	Oskar Axelsson	PN0296	5067

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IP DEPARTMENT
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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	PAPER NUMBER
3768	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,480	AXELSSON ET AL.	
	Examiner	Art Unit	
	KATHERINE L. FERNANDEZ	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,13 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,13 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. (US Patent No. 6,278,893) in view of Kucharczyk et al. (US Patent No. 6,026,316).

Ardenkjaer-Larson et al. disclose a method wherein an invasive device is inserted into a human or non human animal body (column 2, lines 5-10; column 26, line 61-column 27, line 5), comprising the step of providing via the invasive device a therapeutically active compound and via or within the invasive device an MR medium comprising a solution of a hyperpolarized high T1 agent, wherein the high T1 agent is the therapeutically active compound, (column 25, line 32-column 26, line 36) comprising nuclei selected from the group consisting of ^{3}H, ^{3}Li, ^{13}C, ^{15}N, ^{19}F and ^{31}P (column 27, line 64 through column 28, line 16) and having a T1 value of at least 5 seconds at a field strength of 0.001-5 T and a temperature of 20-40 degrees Celcius (column 28, lines 24-26). The invasive device is inserted into a tissue and/or vasculature of the human or non-human body (column 5, lines 30-41). Ardenkjaer-Larson et al. further disclose that the high T1 agent can have a T1 value of at least 10 seconds or more, or 30 seconds or more, or 60 seconds or more, or more than 100 seconds at a field strength of 0.001-5 T and a temperature of 20-40 degrees Celsius (column 28, lines 30-38).

However, they do not specifically disclose that the invasive device is placed in the region in need of treatment and an MR image of at least a part of said body containing said device is generated to visualize said device. They also do not disclose that, if the MR medium is provided within the invasive device, said device contains a cavity for holding the MR medium wherein the cavity is fitted with an outside duct for facilitating circulation and addition of the MR medium. They also do not disclose that the invasive device is made from a medium conductive material containing carbon fiber.

Kucharczyk et al. disclose a drug delivery device for targeted drug delivery into a patient using magnetic resonance imaging combined with conventional catheter placement techniques, particularly including neurosurgical or neuroradiologic techniques used in intracranial drug delivery (column 1, lines 6-16). Their method involves the use of MRI with an MR observable delivery device, with MRI images viewed to determine the position of the delivery or medical device and changes in the environment where the delivery device is present as an indication of changes in the molecular environment, thereby maximizing the safety and efficacy of the procedure (column 6, line 58 through column 7, line 7; column 5, lines 20-28). They disclose that the delivery device must be made of a biocompatible and MR-compatible material such as a carbon fiber composite (column 4, lines 16-35). Targeted delivery of drug agents is performed utilizing MR-compatible pumps connected to variable length concentric MR-visible dialysis probes , or by another MR-compatible infusion device which injects or infuses a diagnostic or therapeutic drug solution (column 8, lines 52-67). They disclose that an MR-visible contrast agent can be injected or infused through the walls of the

dialysis fiber into the brain (i.e. region needing treatment) (column 8, lines 52-67). As can be seen from Figure 1, the drug/contrast agent can be instilled at the region of interest (in this case the brain) via the invasive device (4) (column 16, line 27 – column 17, line 3). Further, as seen in Figures 1-3, their device contains a cavity for holding the MR medium wherein the cavity is fitted with an outside duct for facilitating circulation and addition of the MR medium (Figures 1-3; column 16, line 27-column 17, line 14). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Ardenkjaer-Larson et al. to have the invasive device be placed in the region in need of treatment and an MR image of at least part of said body containing said device be generated to visualize said device, have the device contain a cavity for holding the MR medium wherein the cavity is fitted with an outside duct for facilitating circulation and addition of the MR medium and to have the device be made from a medium conductive material containing carbon fiber, as taught by Kucharczyk et al., in order to maximize the safety and efficacy of the procedure (column 5, lines 20-28).

3. Claims 13, 21-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Kucharczyk et al. as applied to claim 8 above, and further in view of Asai et al. (US Patent No. 5,536,491).

As discussed above, the combined references of Ardenkjaer-Larson et al. and Kucharczyk et al. meet the limitations of claim 8. However, they do not specifically disclose that the high T1-agent is F-uracil, a receptor targeting drug, a bacteriocide or a fungicide. They further do not disclose that the method is a method of therapy by ablation, or that the method is used for the destruction of solid tumors. They also do not

specifically disclose that the high T1 agent is the therapeutically active compound and is a chemical substance effective in ablation. Asai et al. disclose an MRI contrast medium using fluorine as a detectable nucleus. They disclose the use of 5-fluorouracil as an imaging agent and that 5-fluorouracil is a known anti-cancer agent (i.e. chemical substance effective in ablation of tumors) (column 2, lines 46-48; column 34, lines 10-25). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Ardenkjaer-Larson et al. in view of Kucharczyk et al to have the T1-agent be F-uracil and have the method be a method of therapy of ablation for the destruction of solid tumors, as taught by Asai et al., as F-uracil is a known imaging agent and effective in the ablation of tumors (column 2, lines 46-48; column 34, lines 10-25).

4. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Kucharczyk et al. and Asai et al. as applied to claim 24 above, and further in view of Stein (US Patent No. 6,210,655).

As discussed above, the above combined references meet the limitations of claims 25-26. However, they do not specifically disclose that the chemical substance is a carboxylic acid or an alcohol, or that the chemical substance is 13C-enchriced ethanol. Stein discloses site-specific 13C-enriched reagents for diagnostic medicine for magnetic resonance imaging (column 1, lines 7-23). They further disclose that the reagents are targeted to and capable of identifying, quantifying, and localizing disease-specific loci, such as blood clots and tumors (column 1, lines 16-21). The site-specific 13C-enriched reagents may be combined with pharmaceutically acceptable carriers in

amounts effective to produce a detectable magnetic resonance imaging signal, wherein the suitable carrier can be ethanol (column 8, lines 20-36). At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute a carboxylic acid, an alcohol, or 13C-enriched ethanol for the high T1 agent in the method of the above combined references, as taught by Stein, as Stein teaches that 13C-enriched ethanol can be used as an effective MR contrast agent (column 1, lines 7-23).

Response to Arguments

5. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768